REMARKS

The Official Action dated August 25, 2004 and the Advisory Action dated February 28, 2005 have been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 25 and 39 are amended to omit the embodiment wherein only a heavy chain or only a light chain as recited is required, and to direct these claims to the embodiment wherein both a heavy chain and a light chain as recited are required. Claims 26, 28, 30-32, 34-38, 40-42 and 44 are amended to change their dependency, and claims 28, 32, 34, 42 and 44 are amended to omit recitation of the modified version of the Fab and/or the antibody. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

The Advisory Action asserted that the above amendments introduced new matter and new issues into the application as the "proposed amendment of 'human IgG' to claim 26 and 'IgG' to claims 27-28 and 40 raises the issue of new matter and new issue ... because the specification discloses only Phl p2 specific IgE Fab and/or whole Ig," referring to page 4, line 4 of the specification.

Applicants traverse the Examiner's positions. First, Applicants note that the Amendment Under 37 C.F.R. 1.116 to which the Examiner was referring did not propose an amendment to claim 26 or 40 reciting human IgG or amendments to claims 27 and/or 28 reciting IgG. Rather, prior to the proposed amendment, claims 26 and 40 recited human IgG and claims 27 and 28 recited IgG. Moreover, the specification clearly provides support for the group 2 allergen specific human IgG comprising the variable regions of the IgE Fab

which is recited in claims 26 and 40, along with the group 2 allergen specificity. In this regard, the Examiner's attention is directed to the specification at page 3, lines 7-8:

> The present invention also provides group 2 allergen specific human IgG comprising the variable regions of the above IgE Fabs.

The Examiner's attention is further directed to the specification at page 7, lines 20-22:

> Group 2 allergens were detected with Phl p 2-specific IgE Fabs as described for the immunoblotting.

at page 9, lines 22-23:

> Figure 3. rPhl p 2-specific IgE-Fabs crossreact with natural group 2 allergens from different grasses.

and at page 12, line 24-page 13, line 2:

> In order to investigate whether the recombinant human IgE Fabs crossreacted with natural group 2 allergens from different grass and corn species, nitrocellulose-blotted natural pollen extracts from several grass and corn species were tested (Fig. 3). The IgE Fabs reacted strongly with group 2 allergens in sweet vernal grass, rye grass, Kentucky Bluegrass, rye and wheat.

Thus, the present specification clearly discloses the subject matter of claims 26, 27 and 28. Entry of the present amendment is therefore believed to be warranted and is requested.

In the Official Action, claims 45 and 46 were indicated to be allowable. As claims 26-38 and 40-44 now depend directly or indirectly from claim 45 or claim 46, it is believed that these claims are in prima facie condition for allowance. As Applicants previously requested the rejoinder of claims 35-38, and these claims now depend from allowed claim 45, rejoinder of these claims is proper. Accordingly, reconsideration and allowance of claims 26-38 and 40-44 is respectfully requested.

Claims 25-34 and 39-44 were rejected under 35 U.S.C. §112, first paragraph, on the basis that the specification does not reasonably provide enablement for any group 2 allergen specific human IgE-Fabs having a heavy chain or light chain of the respective recited sequence, any group 2 allergen specific human IgG having a heavy chain or a light chain of

the recited sequence, any group 2 allergen specific human IgG directed against any Phl p2, any diagnostic reagent comprising any modified version of the IgG and/or the antibody, any diagnostic kit comprising the reagent, any IgE Fab directed against any Phl p2, or any vaccine comprising any such IgE Fab, any modified version and/or antibody for treating any type I allergy. These claims were also rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventor, at the time the invention was filed, had possession of the claim invention. The Examiner specifically asserted that the specification does not provide a written description of the embodiments for which the specification is asserted to lack enablement. Finally, claims 25-34 and 39-44 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that the recitation of a heavy chain or a light chain in claims 25, 26, 39 and 40 was ambiguous and indefinite because Fab fragments of an antibody require both heavy and light chains.

These rejections are traversed with respect to presently pending claims 25-34 and 39-44. As noted above, claims 25-38 and 40-44 now depend from allowed claim 45 or allowed claim 46, and therefore require the combinations of heavy chain and light chain recited in claims 45 and 46. Additionally, the embodiments directed to the modified versions have been omitted from claims 28, 32, 34, 42 and 44. Thus, claims 26-38 and 40-44 are definite to one of ordinary skill in the art and are fully described and enabled by the present specification, in accordance with the requirements of 35 U.S.C. §112.

Moreover, claim 25 is directed to a group 2 allergen specific human IgE Fab having a heavy chain consisting of an amino acid sequence as shown in SEQ ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9, and a light chain consisting of an amino acid sequence as shown in SEQ ID NO: 10, SEQ ID NO: 11, or SEQ ID NO: 12. Claim 39 is directed to a group 2 allergen specific human IgE Fab having a heavy chain encoded by a nucleic acid sequence as shown

in SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO: 3, and a light chain encoded by the nucleic acid as shown in SEQ ID NO: 4, SEQ ID NO: 5, or SEQ ID NO: 6.

Thus, these claims are directed to IgE Fabs having a heavy chain consisting of a defined amino acid sequence or encoded by a defined nucleic acid sequence, and a light chain of a defined amino acid sequence or encoded by a nucleic acid of a defined sequence. As these claims require both heavy and light chains, the claims are definite in accordance with the requirements of 35 U.S.C. §112, second paragraph. Moreover, the Examiner's attention is directed to the present specification, particularly the description of Fig. 4 beginning at page 10, line 3 which teaches one of ordinary skill in the art that in the IgE Fabs according to the present invention, any of the disclosed heavy chains may be combined with any of the disclosed light chains. Particularly, the specification discloses that the three Phl p2-specific IgE Fabs contain closely related heavy chain fragments which have recombined with different light chains. The sequence comparison discussion which follows on pages 10 and 11 teaches one of ordinary skill in the art that any of the recited heavy chains may be combined with any of the recited light chains as set forth in claims 25 and 39. Moreover, nowhere does the specification indicate that the heavy and light chains must be combined in the manner asserted by the Examiner. It is therefore submitted that claims 25 and 39 are similarly fully enabled by and described in the present specification in accordance with the requirements of 35 U.S.C. §112, first paragraph.

Accordingly, claims 25-34 and 39-44 are fully enabled and described in the present specification and are definite in accordance with the requirements of 35 U.S.C. §112, first and second paragraphs. Reconsideration is respectfully requested.

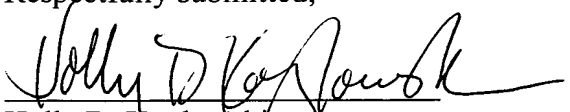
Claims 32, 34, 42 and 44 were rejected under 35 U.S.C. §102 as being anticipated by Steinberger et al, *J. Biol. Chem.*, 271(18):10967-72 (1996). The Examiner referred to Fig. 5B of Steinberger et al with respect to present SEQ ID NO: 10 and Fig. 4 of Steinberger et al

with respect to present SEQ ID NO: 7. Claims 32, 33, 42 and 43 were rejected under 35 U.S.C. §103 as being obvious and unpatentable over Steinberger et al in view of the Frank et al U.S. Patent No. 5,945,294. The Examiner relied on Frank et al as teaching diagnostic kits for IgE detection using human Fc epsilon receptor. The Examiner asserted it would have been obvious to put an antibody as taught by Steinberger et al in a kit as taught by Frank et al for diagnostic assay.

However, Applicants submit that the diagnostic reagents, diagnostic kits, and vaccines defined by the present claims 32-34 and 42-44 are neither anticipated by nor rendered obvious over Steinberger et al, alone or in combination with Frank et al. More particularly, as noted above, these claims now directly or indirectly depend from allowed claim 45 or allowed claim 46. Additionally, the modified versions have been omitted from claims 32, 34, 42 and 44. Accordingly, the diagnostic reagents, diagnostic kits and vaccines defined by these claims are neither disclosed nor suggested by Steinberger et al, alone or in combination with Frank et al. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102, 103 and 112, first and second paragraphs, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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